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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,206	07/18/2003	Thomas P. Osypka	(49363) 58951	2847
21874	7590	07/24/2006	EXAMINER	
EDWARDS & ANGELL, LLP			BERTRAM, ERIC D	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

3766

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,206

Applicant(s)

OSYPKA, THOMAS P.

Examiner:

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-20 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The Applicant stated on page 6 of the Remarks received on 5/10/2006 that appropriate corrections had been made to the specification. However, no amendments were received in the reply. Accordingly, the objection to the specification as described in the Office Action dated 2/16/2006 still stands.

Claim Objections

2. The amendments to claims 18-20 to overcome the objections are acknowledged and accepted. The objections to claims 18-20 are withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5, 6, 17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mclvor et al. (US 6,213,988, hereinafter Mclvor). Mclvor discloses an elongated carrier body 10 for delivering implantable leads to an implantation site (Col. 2, lines 44-46). As shown in figure 4, the carrier body has an interior channel that is open throughout the entire length of the carrier body in order to allow lead 40 to pass through the body. Mclvor also discloses a collar/clamp 22 mounted on the carrier body that can be moved along the length of the carrier body for releasably securing the lead within the open interior channel (see figures 4 and 5).

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5. Regarding claims 5 and 6, if the collar 22 is placed near the distal end of the carrier body, then the distal end portion will inherently be tapered to form a protective shroud around the lead. Furthermore, since the carrier body can be forced by the collar to change shape as shown in figure 5, the body is inherently collapsible.

6. Regarding claims 17, 19 and 20, after the lead is secured to the carrier body and the carrier body is guided to the implantation site, the collar 22 is removed, and the lead is released from the interior channel (Col. 3, lines 27-34).

7. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by McGahan (US 6,095,981). McGahan discloses a device that is capable of delivering implantable cardiac leads to an implantation site. The device includes an elongated carrier body 18 having proximal and distal end portions such that an open channel 20 having a generally U-shaped cross section can accommodate at least one implantable cardiac lead (see figure 1). The carrier body also includes adjustable collar 22 for movement along the circumference of the body, such that the lead is releasably secured within the open channel during delivery to an implantation site (see figures 4-6). While McGahan does not specifically disclose that the device can be used to deliver leads to implantation sites, there are no limitations in the claims of the current application that would preclude it from doing so, and it is the Examiner's position that this is something that the device of McGahan can inherently perform.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mclvor in view of Ricciardelli et al. (US 4,644,957, hereinafter Ricciardelli). Mclvor, as described above, discloses the applicant's basic invention, including delivering leads to implantation sites. Mclvor does not disclose, however, a journaled handle assembly for effectuating axial rotation of the carrier body. Attention is directed to the secondary reference of Ricciardelli, that discloses a journaled handle assembly comprising handle 15, shaft 16, and carrier body 10, such that by gripping the handle, the carrier body could then be axially rotated around the shaft by turning the body (see figure 1 and Col. 6, lines 22-26). Since Mclvor must first tear the carrier body to remove it from the lead, it would be helpful to be able to rotate the carrier body in order to assist in its removal from the lead. Therefore, it would have been obvious to one of ordinary skill in the art to modify the delivery system of Mclvor by including the journaled handle assembly of Ricciardelli in order to assist in the removal of the torn carrier body from surrounding the lead.

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11. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIvor in view of Brucker et al. (US 5,500,012, hereinafter Brucker). McIvor, as described above, discloses the applicant's basic invention with the exception of the carrier body having mapping electrodes and the distal end portion being configured for articulated movement using means at the proximal end. Attention is directed to the secondary reference of Brucker, which discloses a catheter for delivering an ablation electrode to the heart (Col. 3, lines 40-46). The catheter has electrodes 22a-22n at the distal tip that provide local activation mapping (Col. 3, lines 49-52), and the distal end is also configured for articulated movement by pulling on wire 25 at the proximal end (Col. 4, lines 7-10 and 44-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to add mapping electrodes and articulated movement in order to locate the best treatment site and then maneuver the tip into the best position to deliver treatment (Col. 2, lines 20-25 and Col. 3, lines 62-63).

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGahan in view of Ricciardelli. McGahan, as described above, discloses the applicant's basic invention, with the exception of including a journaled handle assembly for effectuating axial rotation of the carrier body. Attention is directed to the secondary reference of Ricciardelli, that discloses a journaled handle assembly comprising handle 15, shaft 16, and carrier body 10, such that by gripping the handle, the carrier body could then be axially rotated around the shaft by turning the body (see figure 1 and Col. 6, lines 22-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the device of McGahan by adding a

journaled handle in order to allow one to rotate the carrier body without rotating the entire device in order to place the lead in the preferred implantation site.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGahan. McGahan, as described above, discloses the applicant's basic invention with the exception of tapering the distal end of the carrier body, which already partially shrouds, or covers, the distal end of the lead. However, as stated on page 9, line 21 of the applicant's disclosure, the end is tapered in order to prevent an atraumatic surface to body tissue as the carrier body is advanced. It is well known in this art, and in general, that a tapered body, due to its lack of blunt edges, is easier and safer to insert into any tight fit. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the distal end of McGahan by tapering the carrier body in order to create a more streamlined carrier body for insertion into the body.

14. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGahan in view of Brucker et al. (US 5,500,012, hereinafter Brucker). McGahan, as described above, discloses the applicant's basic invention with the exception of the carrier body having mapping electrodes and the distal end portion being configured for articulated movement using means at the proximal end. Attention is directed to the secondary reference of Brucker, which discloses a catheter for delivering an ablation electrode to the heart (Col. 3, lines 40-46). The catheter has electrodes 22a-22n at the distal tip that provide local activation mapping (Col. 3, lines 49-52), and the distal end is also configured for articulated movement by pulling on wire 25 at the proximal end (Col.

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4, lines 7-10 and 44-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to add mapping electrodes and articulated movement in order to locate the best treatment site and then maneuver the tip into the best position to deliver treatment (Col. 2, lines 20-25 and Col. 3, lines 62-63).

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mclvor. Mclvor, as described above, discloses the applicant's basic invention including delivering leads to an implantation site. In order to do so, Mclvor discloses that the carrier body can be torn so that the lead may be left in the appropriate site. Mclvor describes how handles 14 are used to separate the carrier body at weakened zones 18, but is silent as to the exact method used. One possible and obvious technique to be used would be to grip each handle and then turn the handles in opposite directions in order to break the carrier body at the weakened zones. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to rotate the carrier body in order to facilitate the deployment of the lead at the implantation site since Mclvor is silent as to how the lead is released and this method would be both plausible and obvious.

Allowable Subject Matter

16. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

17. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766

EDB



Robert E. Pezzuto
Supervisory Patent Examiner
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